SIERRA CLUB
FOUNDED 1892

March 18, 2001

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
room 1061
Rockville, MD 20852

Re: Docket No. 00N-1396

Dear Sirs:

The following comments are prepared by the Sierra Club, our nation's oldest and largest grassroots environmental organization with 600,000 members, to address the FDA's proposed rules titled "Premarket Notice Concerning Bioengineered Foods." Our comments will, of course, be directed in large part from our stance as a protector of the natural environment. We would like to remind the Agency, however, that there are no rigid dividing lines between human health, quality of life, and environmental quality. Without asking that your Agency overstep its statutory authorities, we will urge that future regulations and their manner of implementation be guided by a broad perspective which includes environmental as well as human health concerns, and which maximizes interagency cooperation to address all of these concerns.

We have also prepared comments responsive to Docket No. 00D-1598 regarding labeling of bioengineered foods.

While the mandatory nature of the letter you propose to require is a step forward, there is still the underlying presumption that the consultation with FDA is for the purpose of assuring that the food is safe for consumers and in compliance with legal requirements. This has not changed from your 1992 policy. We submit that this is an inadequate foundation for review since it omits environmental impacts.

While the EPA may review pesticide-containing crops, rDNA technology raises questions of genetic outflow into nature (among other questions) which also need to be addressed by any regulatory scheme. The FDA has not required that any information regarding outcrossing with native species or weedy relatives be included in the letter. We believe that such information should be sought. Indeed, we believe that an environmental impact statement should be a part of the required regulatory sequence.

Therefore, our position is that the present "Premarket Notice" fails to remedy the fragmentation of oversight which currently exists and fails to adequately address environmental concerns.

Another underlying supposition in the FDA's proposed process is that "transferred genetic material can be presumed to be GRAS." The FDA's argument here is that if the intended addition is not present in the bioengineered food in excess of its presence in other currently consumed foods, that it can be presumed GRAS. Sierra Club believes that this argument is weak in that the transfer of genetic material also includes a promoter gene and marker genes, that the transfer may impinge on other regulatory mechanisms of the plant, that it may be unstable over

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time, and that the emphasis is on the food consumed by humans and farm animals and therefore overlooks possible environmental impacts.

With regard to promoter and marker genes, our point is that the FDA must not evaluate the GRAS question only with regard to the intended change but with regard to any other changes, also including pleiotropic effects. We are glad that you address that question elsewhere.

Furthermore, the concept of GRAS serves to protect humans better than the environment. What's GRAS for humans might not be safe other species. A migrating songbird which eats grain remaining on the ground after harvesting, for instance, might be harmed by levels of a hormone mimic which are easily tolerated by humans. An added amount of anything, therefore, which is significantly more than previously present in the particular food in question, should trigger environmental impact assessments.

We support your view that an allergen, however, "that would not be expected to be in a particular food," must be regarded as an additive to be labeled or an adulterant.

We support your views regarding the labeling of compositional changes in foods, where new metabolic pathways have been added which result in the synthesis of substances not normally present, and also your statement that "with the increased introduction of multiple genes, unintended effects may become more common," and that these may "raise adulteration or misbranding questions." This, indeed, was our point in mentioning pleiotropic effects above. We believe that, because of the prevalence of pleiotropic effects, that there should be no suppositions made regarding GRAS status. With our present technological sophistication, crops could be tested with gene chips to check on the activity of various regulatory pathways. An excess of caution would be far better than the assumption of safety.

The FDA has requested comment as to whether it should include foods from crops developed by wide crosses or other breeding methods in the scope of any final rule. We believe that it should because the combination of such other breeding methods together with genetic sequencing, and the possible accumulation of altered genetic code due to it's bioaccumulative potential, may make it impossible to draw a line between technologies.

We are alarmed by your statement that since "many [modifications by rDNA] will result in a food that does not contain an unapproved food additive, does not contain an unexpected allergen, and does not differer significantly in its composition" that "FDA is neither proposing to require premarket approval for all foods developed using rDNA technology nor is the agency proposing an across-the-board requirement that all such foods bear special labeling." This appears to mean that although the letter which you are requiring is mandatory, that pre-market approval is not, and that unapproved foods might be marketed. Sierra Club finds this totally unacceptable.

Sierra Club's official policy is that there should be a mandatory pre-market evaluation (and also post-marketing surveillance), that this should include both human health and environmental issues, that the public should be involved, that the process be transparent, that trade secrecy provisions shouldn't be used to hide any issues, and that all such foods be labeled.

We do not believe that "mandatory consultation" consisting of a mandatory letter writing requirement is meaningful in the absence of mandatory approval prior to marketing!

Your argument that the Agency should subject bioengineered foods to increased scrutiny is unobjectionable, but your statement that "the food products of rDNA technology are appropriately made subject to greater regulatory scrutiny by FDA in the form of enhanced agency awareness of all such foods intended for commercial distribution" is inadequate. We agree that the Agency would have the authority to regulate, but believe that your regulations should insist that you will use that authority in each case.

In the absence of mandatory pre-market approval, the 120 day period is apt to become unworkable. If only notification is required and it becomes ordinary for letters to be written but no action taken, then both health and environmental issues can be easily obscured. This is especially true because the official notifications may, under your proposed rules, include claims of trade secrecy. Non-governmental organizations like Sierra Club deserve information and a chance to be heard, and this will be made much more difficult by the incentive (to those writing the premarket notification letters) to write opaque last-minute notifications and try to shield negative information as trade secrets. A mandatory approval mechanism would discourage such behaviors and make it easier to stop the clock when there was inadequate information.

We have replied separately to Docket No. 00D-1598 regarding our position on labeling of bioengineered foods. The comments therein are certainly relevant to this Docket as well.

With regard to "excluding a bioengineered food that meets three specified criteria" from notification: we believe this is unwise at multiple levels. Genetic material is not merely put into plants by genetic engineers. Since crops are planted over millions of acres and various "transformation events" may, over time, leave hundreds of different genetic alterations in play, regulation cannot be by "event." Interactions will become more and more complex over time, and pollination rather than laboratory intervention may come to play the more significant role. It will be important, therefore, to proceed on a case-by-case basis. This should be built into the regulations now, not added later.

We have stated our strong belief that post-marketing surveillance is important. Exclusion of the type envisioned hereabove would result in losing some readily obtainable post-marketing surveillance, because new applications might well contain information regarding genetic instability or admixtures of traits through natural processes like pollination. Indeed, such information should be proactively sought.

Regarding the proposed 120 day period: it would be acceptable only if approval were mandatory so that there would be a reasonable expectation by the public and the applicants that the clock would stop if inadequate information had been supplied.

Regarding the statements about trade secrecy and the FOIA, Sierra Club believes that good regulation is not possible without full information, and that the information which FDA needs for regulation is properly public information. Certainly having such information available 120 days before marketing exposes companies to almost no risk of wrongful appropriation of intellectual property.

We can see that using crops to produce pharmaceuticals in the future may result in more claims of trade secrets. We do not believe that the present rules are intended to address the many concerns which we would have about outdoor production of pharmaceuticals. With respect to the trade secrecy question alone: we would strongly oppose dual use of a crop for both drug production and food unless trade secrecy provisions have been waved and full disclosure made. The review for "out of doors" production of pharmaceutical agents would necessarily be more intensive (and would require far more than 120 days!), and trade secrecy would be correspondingly less appropriate.

The statement about a required synopsis contains this language: "FDA is proposing to recommend this synopsis because the agency believes that the information in the synopsis is both necessary and sufficient to characterize the bioengineered food in a manner that will enable the agency to engage in meaningful dialogue with the prospective notifier." We have no objection to the inclusion of the synopsis, but we don't believe that the information asked for can be characterized as "sufficient" for anything but opening a dialogue.

We are supportive of the Agency's proposal to require an electronic disclosure copy of a PBN, which will make sharing information (both within the Agency, with other governmental bodies, and with the public) quicker and easier. Regarding waivers: they should not be granted.

FDA has requested comment on "technological advances in rDNA technology that are likely to result in commercial products and that would not be addressed to by proposed submission requirements." We are confining our comments to foods derived from plants (although Sierra Club is very concerned with aquaculture, forestry, and "pharming"). Speaking very generally, the biggest technological deficiency in genetic engineering techniques at present is poor regulation of the expression of inserted genes. It's therefore only reasonable to assume that more elaborate regulatory schemes will be attempted in the future. Indeed, GURTs represent a primitive approach to switchable genes, and disease researchers often target specific sequences to a specific location on the genome. Since the full-time production of a protein which may not be needed (such as Bt aimed at an infestation of ECB which may not occur) is obviously inefficient, we would expect to see many more gene-regulatory features included in future products. Many of these may represent very complex packages in which the seed manufacturer builds in "capability" and then sells a service, using proprietary chemicals to induce transcription at specific times during a plant's life cycle or in response to specific environmental conditions or pests.

We do not believe that the present proposed rules are sufficient even for the products of today, and they would be totally inadequate to the review of products such as those mentioned.

We are glad to see that, among other requirements of the notification, will be status at other federal agencies and foreign governments. A coherent program of regulation with fewer gaps between FDA and other agencies (EPA, USDA/APHIS) is clearly needed, and this will be a help.

We do not disagree with your statements regarding allergenicity, except that labeling and post-marketing surveillance seem to us to be a requisite part of identifying such problems. We think that it's highly absurd to recognize that the problem is a significant one and to deal with it at the level of protein structure, yet at the same time to refuse to look for prevalence or incidence by the practical means of mandatory labeling and post-marketing surveillance.

Regarding allergenicity, we also believe that farm workers and other food production workers need to be considered as well as ultimate consumers. Of special concern is that processing (such as milling) of food may release respiratory allergens. Such effects need to be looked for proactively.

The FDA has requested comments regarding whether the premarket notice should include methods for detection of the bioengineered food. We believe that it should, and that no bioengineered food should be marketed without the ready availability of a sensitive and specific detection system for the protein(s) encoded by all transformation events.

The FDA's discussion of its possible actions in the event that a notifier decides to market a bioengineered food before receiving approval shows that the Agency has significant powers, and an awareness of them, to deal with such situations. We certainly hope that it will always have sufficient motivation, sufficient support from other levels of government, and sufficient budget to make use of these powers. We also believe the FDA will need more specialists in the evaluation of environmental impacts, and this would also require additional funding. We also believe that public science should be directed to many of the outstanding questions, and much of

that should be federally funded. The FDA should certainly have a role in the prioritization of such research.

In summary, Sierra Club supports mandatory labeling so that consumers can have a choice. That choice may be based on perceived personal safety issues, but may also be based on environmental concerns.

We call for environmental impact statements for every crop and new location. There should be no exemption from environmental review procedures under the National Environmental Policy Act.

No genetically engineered crops should be presumed as GRAS; both human and animal safety evaluations, in addition to environmental impact statements, are needed for each new bioengineered crop.

We believe that we in the U.S. should enjoy the same protection, via labeling, that has already been enacted in Japan, Korea, and most of Europe.

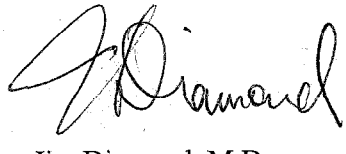
We believe the since agricultural markets are global, that many American farmers are placed at a disadvantage by the absence of segregation and labeling, and that the present FDA proposals serve seed companies at the expense of farmers.

The burden of crop segregation and labeling expenses should fall on those who are introducing this new technology. (The responsibility for contamination of crops by pollen spread must also be borne by the introducers and adopters of the new technology.)

We call for truly mandatory procedures—not just the writing of a mandatory letter. No bioengineered crops should be marketed without approval. During the period in which the FDA is considering an application, public meetings must be held and public comments solicited and considered.

The provisions to have most of the submitted information available in electronic reading rooms is good, but we call for a elimination of any trade secrecy provisions which would limit public access to the information during the public comment period. While business plans for the future may sometimes be a legitimate trade secret, information on the composition and safety a product pending licensing, including studies in progress or negative studies, must be made known.

Respectfully submitted,



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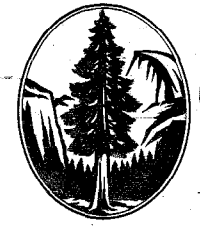

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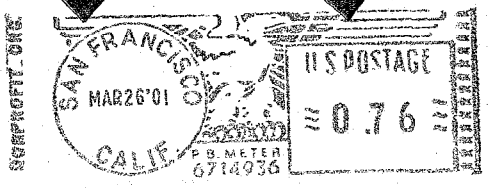

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